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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,541	12/05/2003	D. Bruce Modesitt	6771USC1	1905

23492 7590 12/12/2006

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/729,541		MODESITT ET AL.	
	Examiner		Art Unit	
	Julian Woo		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-37 are rejected under 35 U.S.C. 102(e) as being anticipated by

Andreas et al. (6,036,699). Andreas et al. disclose, at least in figures 1-2B and 4-8 and in col. 9, line 44 to col. 11, line 43; a device and a method with the device for closing an opening (A) in a tissue or blood vessel, where the device and method include a shaft (402, or with respect to claim 5, a tubular element (unlabeled) attached to element 406 and internal to element 426 as seen in figs. 2A and 2b) having a proximal end and a distal end, a foot (426, or 404 with respect to claim 6) on the distal end of shaft that is movable with respect to the shaft, and a flexible guidebody (404, or 426 with respect to claim 6) defining a guidewire (442) lumen (within 404 or 426) or a suture storage lumen (within 426), where the flexible guide body defines a guidewire entry port at its distal end (an opening at the distal end of element 426) and an exit port proximal to the entry port (an opening at the proximal end of element 426), where the exit port is situated at a location distal to the distal end of the shaft (402), where a portion of the shaft (the tubular element (unlabeled) attached to element 406) curves such that the flexible guide

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body extends from the shaft at an angle relative to an axis of the shaft, where the device includes a length of suture (422) supported by the foot, where the flexible guidebody (426) defines a lumen with the suture extending therethrough, where a needle (410) is advanceable from the shaft through tissue and to the foot when the foot is moved to deployed position (i.e., the needle is movable distally to the foot (retractable--according to col. 10, lines 24-31)), where the method includes partially withdrawing the flexible guidebody (404 or 426) from a tissue opening to reduce a flow of blood through the opening (see col. 11 lines 11-14); where the method includes moving the foot from a parked position to a deployed position (see figs. 1 and 4), forming a needle path from the shaft through the tissue (the path extending from needle lumen 420 to guide channel 408), advancing suture along the needle path, securing a suture loop to close the opening (see fig. 8), and fully withdrawing the flexible guidebody from the opening after the loop is at least partially secured (see fig. 6); where the opening is accessed through subcutaneous tissue; where the flexible guidebody (404) extends from the shaft at an angle relative to an axis of the shaft (402) and positioned coaxially within the blood vessel, while the shaft is positioned coaxially within a tissue tract, and where the foot (426) is aligned with the blood vessel when in the deployed position.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kensey (4,744,364), Shaknovich (5,749,890), and Kontos (5,928,266) teach devices for closing tissue openings.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

December 11, 2006